REMARKS

The present application is directed to a method for treating Alzheimer disease in a patient. Prior to the present Response, Claims 17-39 were pending. In this Response, Applicants cancel Claims 20, 23 and 28-39 and amend Claims 17, 21, 22 and 24. The amendments do not add any new matter. The amendments to Claim 17 are based on now cancelled Claim 23. The amendments to Claims 21, 22 and 24 correct the claim dependencies. Claims 17-19, 21, 22 and 24-27 will be pending upon entry of the amendments.

Objection to the Oath/Declaration

The Examiner objects to the Oath/Declaration as defective. Applicants will submit a new Oath/Declaration.

Rejection of Claims under 35 U.S.C. §112, First Paragraph

The Examiner rejects Claims 28-39 under 35 U.S.C. §112, first paragraph, for insufficient enablement. In this Response, Applicants cancel Claims 28-39, thereby rendering their rejection moot. Applicants request withdrawal of the rejection.

Rejection of Claims under 35 U.S.C. §112, Second Paragraph

Rejection of Claims 17-22, 25-33 and 36-39

The Examiner rejects Claims 17-22, 25-33 and 36-39 under 35 U.S.C. §112, second paragraph, as indefinite. *See* page 10 of the Office Action. The Examiner asserts that the phrase "naturally occurring plasma," recited in Claims 17-22, 25-33 and 36-39, is indefinite. In this Response, Applicants cancel the rejected Claims 20, 28-33 and 36-39, thereby rendering their rejection moot. In the Office Action, the Examiner states that Claims 23-24 and 34-35 are not subject to the rejection because the claims specifically recite that the "naturally occurring plasma" is yielded from the separation of blood cells from the whole blood obtained from a patient. Applicants therefore amend Claim 17 to recite the steps of "withdrawing blood containing blood cells from the patient" and "separating the blood cells from the blood to yield naturally occurring plasma from the patient." Applicants cancel Claims 20 and 23 as redundant in view of amendments to Claim 17. Applicants assert that the claims, as currently amended, are

definite and that the amendments overcome the rejection of Claims 17-19, 21, 22 and 25-27. Applicants request withdrawal of the rejection.

Rejection of Claims 26 and 37

The Examiner asserts that Claims 26 and 37 are indefinite because they recite a subject with increased blood cholesterol, without defining a standard for ascertaining what "increased" means. In this Response, Applicants cancel Claim 37, thereby rendering its rejection moot. Applicants traverse the rejection of Claim 26. Applicants assert that "increased cholesterol" is a term that was well understood by one of ordinary skill in the art in the field of the present application at the priority date of the present application, as evidenced by the attached Exhibit A, an article by Price *et al.* "Observed changes in the lipid profile and calculated coronary risk in patients given dietary advice in primary care." *The British Journal of General Practice*, v. 50, pp. 712–715 (2000). *See*, for example, the section "*Method*" beginning on the bottom of p. 712. Applicants therefore assert that the term "increased blood cholesterol levels," as recited in Claim 26, is definite. Applicants request withdrawal of the rejection.

The Rejection of Claims under 35 U.S.C. §103(a)

The Examiner rejects Claims 17-27 and 39 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,895,558 in view of Simons *et al.*, *Neurology*, v. 57, pp. 1089-1093 (2001) ("Simons"). *See* page 12 of the Office Action. The Examiner states that, based on the disclosure of Simons, one of ordinary skill in the art at the time of the invention would have found it obvious to employ the autologous plasma delipidation process disclosed in U.S. Patent No. 4,895,558 in a patient suffering from Alzheimer's disease. Applicants cancel the rejected Claims 20, 23 and 39, thereby rendering their rejection moot. Applicants traverse the rejection of Claims 17-19, 21, 22 and 24-27.

A *prima facie* case of obviousness based on a reference or references must meet three basic criteria: (1) suggestion or motivation to modify the reference or to combine the references' teachings; (2) a reasonable expectation of success from such a combination or modification; and, (3) the reference or references must teach or suggest all the claim limitations. *See* MPEP 2141.01(a) and 2142. *See also KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741

(U.S. 2007) and *Leapfrog Enters., Inc., v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007). The rejection based on a combination of U.S. Patent No. 4,895,558 and Simons does not meet at least one of the required *prima facie* obviousness criteria, showing of suggestion or motivation to modify the reference or to combine the references' teachings.

Simons fails to teach, suggest or provide motivation to use a plasma delipidation process, as disclosed in U.S. Patent No. 4,895,558 or as recited in the currently pending claims, to treat Alzheimer's disease in a patient. U.S. Patent No. 4,895,558 fails to teach, suggest or provide motivation to use the autologous plasma delipidation process that it discloses to treat Alzheimer's disease in a patient. Accordingly, Simons or U.S. Patent No. 4,895,558, separately or in combination, fail to render obvious the pending claims, which recite administering partially delipidated plasma to a patient in order to treat Alzheimer's disease in the patient. Applicants therefore respectfully assert that the Examiner failed to establish a *prima facie* case of obviousness. In view of the foregoing, Applicants request withdrawal of the rejection.

Obviousness-Type Double Patenting

Claims 17-27 and 39 are rejected on the grounds of nonstatutory obviousness-type double patenting over Claims 1-3 of U.S. Patent No. 4,895,558, Claims 1-12 of U.S. Patent No. 5,744,038, Claims 1-48 of U.S. Reissue Patent No. RE 37,584, and Claims 1-8, 19-33, and 41-47 of U.S. Reissue Patent No. RE 39,498, each in view of Simons. Applicants cancel the rejected Claims 20, 23 and 39, thereby rendering their rejection moot. Applicants traverse the rejection of Claims 17-19, 21, 22 and 24-27.

As provided in MPEP 804(II)(B)(1), the analysis for an obviousness-type double patenting determination uses the following factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) for determining obviousness:

(A) Determine the scope and content of a patent claim relative to a claim in the application at issue;

(B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

The patent claims cited by the Examiner are directed to methods of removing cholesterol, triglycerides or lipids from blood or plasma, or to methods of reducing cholesterol, triglycerides or lipids in blood or plasma. None of the cited patent claims teach, suggest or provide motivation to apply the methods they recite to treating Alzheimer's disease in a patient. Simons also fails to teach, suggest or provided motivation to use the methods recited in the cited patent claims or in the currently pending claims to treat Alzheimer's disease in a patient. Accordingly, the patent claims cited by the Examiner and the disclosure provided in Simons, separately or in combination, fail to teach, suggest or provide motivation to combine any of the cited patent claims with the teaching of Simons to arrive at the currently pending claims.

Thus, Claims 1-3 of U.S. Patent No. 4,895,558, Claims 1-12 of U.S. Patent No. 5,744,038, Claims 1-48 of U.S. Reissue Patent No. RE 37,584, and Claims 1-8, 19-33, and 41-47 of U.S. Reissue Patent No. RE 39,498, or Simons, separately or in combination, fail to render obvious the pending claims. In view of the foregoing, Applicants request withdrawal of the rejection.

CONCLUSION

The foregoing is submitted as a full and complete response to the Non-Final Office Action mailed July 24, 2007. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies that may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to Dr. John McDonald at (404) 745-2470 is respectfully solicited.

Respectfully submitted,

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